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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,727	10/26/2001	John E. Sims	3151-A	9375

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 IMMUNEX CORPORATION  
 LAW DEPARTMENT  
 1201 AMGEN COURT WEST  
 SEATTLE, WA 98119

EXAMINER
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LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/061,727

Applicant(s)

SIMS ET AL.

Examiner

Ruixiang LI

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 8, and 12-14 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2 and 7 is/are allowed.
- 6) ☒ Claim(s) 5, 6, 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11282003. 6) ☐ Other:

## **DETAILED ACTION**

### **I. Status of Application, Amendments, and/or Claims**

The amendment filed on November 28, 2003 has been entered in full. Claims 2, 5, and 9 have been amended. Claims 1-14 are pending. Claims 1, 2, 5(in part), 6 (in part), 7, 9 (in part), 10(in part), and 11 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **II. Information Disclosure Statement**

The Information Disclosure Statement filed on November 28, 2003 has been considered by the Examiner and a fee of \$180 as set forth in §1.17(p) has been charged to Deposit Account No. 09-0089.

### **III. Withdrawn Objections and/or Rejections**

The rejection of claim 9 under 35 U.S.C. §101, as set forth at page 3 of the previous office action (Paper No. 8, May 29, 2003) has been withdrawn in view of Applicants' argument.

The rejection of claims 5, 6, 9, and 10 under 35 U.S.C. §112, 1<sup>st</sup> paragraph, as set forth at pages 3-6 of the previous office action (Paper No. 8, May 29, 2003) has been withdrawn in view of Applicants' amendment to the claims.

The rejection of claim 5 under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, as set forth at pages 9-10 of the previous office action (Paper No. 8, May 29, 2003) has been withdrawn in view of Applicants' argument.

The objection of claim 2 for minor informalities, as set forth at page 11 of the previous office action (Paper No. 8, May 29, 2003) has been withdrawn in view of Applicants' amendment to the claim.

#### **IV. Claim Rejections under 35 USC § 112, 1<sup>st</sup> paragraph (Description)**

The rejection of claims 5, 6, 9, and 10 under 35 U.S.C. §112, 1<sup>st</sup> paragraph for Description, as set forth at pages 6-8 of the previous Office Action (Paper No. 8, May 29, 2003), is maintained.

Applicants' amendment filed on November 28, 2003 has resolved all the issues except the problem related to claim 5, part h), which recites an isolated nucleic acid molecules that hybridizes to either strand of a denatured, double-stranded DNA comprising the polypeptide of any one of e-g *under conditions of moderate stringency*; wherein the isolated nucleic acid encodes a polypeptide that interacts with an IL-1R signal transduction factor.

Applicants argue that claim 5, part h) requires that the variant interact with an IL-1R signal transduction factor. Those skilled in the art know that in order to preserve the

functional ability to interact with these factors, the number of variants is in fact small (bottom of page 7 to top of page 8 of Applicants' response). Applicants further submit that Example 9 of the PTO's Written Description Guidelines supports this position (3<sup>rd</sup> paragraph of page 8 of Applicants' response).

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the amended claim, while reciting a functional limitation, still encompasses a genus of nucleic acid that may be structurally unrelated, due to the hybridization *conditions of moderate stringency*. The claims do not require that the nucleic acid possess any particular conserved structure or other distinguishing feature. The specification fails to disclose the structural feature or correlation of structure to function of the claimed genus of the nucleic acid, or a representative number of species of the claimed genus. It is noted that a definition by function does not suffice to define the genus because it is only an indication of what the genus does, rather than what it is.

Secondly, the PTO's Written Description Guidelines do not support Applicants' position because Example 9 of the PTO's Written Description Guidelines refers to an isolated nucleic acid that hybridizes under highly stringent conditions, not *under conditions of moderate stringency* which an artisan would expect to yield structurally unrelated nucleic acid molecules and to produce substantial variations among species encompassed within the scope of the claims.

**V. Claim Rejections under 35 USC § 112, 2<sup>nd</sup> paragraph**

(i). The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 11 are indefinite because it is unclear what protein is to be made by the process; the claims, as written, read on any proteins produced by the cell.

It is noted that this is a new ground rejection.

**VI. Claim Rejections under 35 USC § 102**

(i) The rejection of claims 5, 6, 9, and 10 under 35 U.S.C. 102(b) as being anticipated by Saeki et al. (Database Swiss-Prot, Accession No. P35413, November 1, 1997), set forth at pages 10-11 of the previous office action (Paper No. 8, May 29, 2003), is maintained.

Applicants argue that Applicants amended claim 5, part h) to reference the polynucleotides of parts e)-g). In doing so, only the unique novel portion of the splice variant forms the basis for the hybridization polynucleotides.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. Claim 5, part e), recites a polynucleotide that encodes a polypeptide comprising amino acid residues 449-687 of SEQ ID NO: 2 and

thus encompasses the polynucleotide set forth in SEQ ID NO: 1. Huang et al. teach a cDNA, which encodes a interleukin 1 receptor accessory protein (that interacts with an IL-1R signal transduction factor) comprising the amino acid residues 1 to 448 of SEQ ID NO: 2 and shares 51.7% sequence identity with SEQ ID NO: 1. Thus, this cDNA would hybridize to the polynucleotide of SEQ ID NO: 1 under conditions of moderate stringency as recited in the claim 5, part h), meeting the limitations of claim 5, part h). Claims 6, 9, and 10 depend from, either directly or indirectly, from claim 5, h).

(ii) The rejection of claims 5, 6, 9, and 10 under 35 U.S.C. 102(e) as being anticipated by Cao (US Patent No. 6,280,955), set forth at page 11 of the previous office action (Paper No. 8, May 29, 2003) remains. It is noted that Applicants are correct in that this rejection is a 102(e) rejection, not a 102(b) rejection.

Applicants argue that in view of the amendment to claim 5, part h) to reference the polynucleotides of parts e)-g), the rejection has been overcome.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. Claim 5, part e), recites a polynucleotide that encodes a polypeptide comprising amino acid residues 449-687 of SEQ ID NO: 2 and thus encompasses the polynucleotide set forth in SEQ ID NO: 1. Cao teach a cDNA, which encodes a interleukin 1 receptor accessory protein (that interacts with an IL-1R signal transduction factor) comprising the amino acid residues 1 to 448 of SEQ ID NO: 2 and shares 51.7% sequence identity with SEQ ID NO: 1. Thus, this cDNA would hybridize to the polynucleotide of SEQ ID NO: 1 under conditions of moderate

stringency as recited in the claim 5, part h), meeting the limitations of claim 5, part h).  
Claims 6, 9, and 10 depend from, either directly or indirectly, from claim 5, h).

#### **VII. Claim Objections**

The objection of claims 5, 6, 9, and 10 for reciting unelected subject matter related to SEQ ID NO: 4 remains. It is noted that Applicants have not amended claim 5 to remove the unelected subject matter. Appropriate correction is required.

#### **VIII. Conclusion**

Claims 1, 2, and 7 are allowed.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Ruixiang Li  
Examiner  
February 17, 2004



LORRAINE SPECTOR  
PRIMARY EXAMINER